

# MHRA Drug Safety Update

November 2021



## Adrenaline auto-injectors: reminder for prescribers to support safe and effective use

Emerade 300 and 500 microgram adrenaline auto-injectors have been re-supplied to the market following the implementation of corrective actions. In 2020, Emerade adrenaline auto-injectors were recalled from patients and pharmacies due to an error in one component that caused some auto-injectors to fail to activate and deliver adrenaline.

The MHRA has reviewed the Marketing Authorisation Holder's results from its investigation into activation failures and the subsequent implementation of corrective actions. The MHRA has confirmed that 300 microgram and 500 microgram strengths of the Emerade auto-injectors can be re-introduced in the UK. In October 2021, a letter was sent to healthcare professionals to inform them of the reintroduction.

The Emerade 150 microgram auto-injector will not be returning to market at this time, further details will be provided at a later date.

### Advice for healthcare professionals:

- Emerade 300 microgram and 500 microgram adrenaline auto-injectors have been resupplied to the market following the implementation of corrective actions to resolve the issue that caused some devices to fail to activate and deliver adrenaline
- For each adrenaline auto-injector, follow advice in the Summary of Product Characteristics to prescribe appropriate doses for individual patients (see section on dosing considerations)
- Remind patients to follow existing advice to carry 2 in-date adrenaline auto-injectors with them at all times and to replace them before they expire
- Provide patients and their caregivers with training and advice specific to their prescribed adrenaline auto-injector; encourage them to order a trainer device from the manufacturer to ensure they are familiar with using their auto-injector
- Suspected adverse drug reactions or defective medicines should be reported to the Yellow Card scheme

### Advice for healthcare professionals to provide to patients:

- The 300 and 500 microgram strengths of Emerade are being made available again, following corrections made to the auto-injector device
- The Epipen and Jext brands of adrenaline auto-injector in a strength of 300 microgram continue to be suitable alternatives to the Emerade 500 microgram adrenaline autoinjector; this has been confirmed by measurement of adrenaline blood levels following administration
- It is vital to carry 2 in-date adrenaline auto-injectors with you at all times and replace them before they expire
- Make sure you and your caregivers know when and how to use your adrenaline autoinjector before you need to use it in an emergency; practice with a training device so you are familiar with how your particular auto-injector works
- Always read the Patient Information Leaflet that accompanies your medicines and ask your doctor, nurse, or pharmacist if you have any questions
- You should use your adrenaline auto-injector as soon as you suspect a severe allergic reaction (anaphylaxis), especially any signs affecting your airway (swelling of your tongue or a feeling of constriction in your throat), breathing (wheezing, difficulty in breathing), or your circulation (feeling faint, dizzy, cold clammy skin)
- At first signs of anaphylaxis:
  1. Use an adrenaline auto-injector immediately; do not delay
  2. Call 999, ask for an ambulance, and say ana-phy-l-ax-is (even if symptoms appear to be improving after using an auto-injector)
  3. Lie down and raise your legs
  4. Use a second auto-injector if your symptoms haven't improved after 5 minutes
  5. Lying down is important to keep blood flowing to your organs; you can sit up if you are struggling to breathe, but keep your legs elevated as far as possible and lie back down again as soon as you can